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Plan for a National Environmental Specimen Bank

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16. ABSTRACT

The U.S. Environmental Protection Agency (EPA) has been concerned about the potential dangers to human health and the environment from the ever increasing flux of new man-made substances into our ecosystem. Since 1974, the EPA has been actively engaged in studying the feasibility of establishing a program, The National Environmental Specimen Bank (NESB), that would provide a formalized, systematic approach to assess the environmental impact of these substances at a national, as well as international level. The NESBS would provide real time monitoring, assessing the adequacy of present pollutant control techniques, as well as providing samples for retrospective analyses.

With the realization that NESBS is a viable concept, both from the standpoint of need and by the availability of present technology, it must be decided if such a system is, in fact, feasible to establish and maintain under actual operating conditions. It is proposed, therefore, that a five-year pilot bank program be initiated. During this time, a limited number of samples should be collected, analyzed, and stored in a central facility. The pilot bank program should focus on validating credible collection, storage, and analytical data. The functioning NESBS should provide future generations with an important resource for evaluating their current environmental status.

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34

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FOREWORD

The many benefits of our modern, developing, industrial society are accompanied by certain hazards. Careful assessment of the relative risk of existing and new man-made environmental hazards is necessary for the establishment of sound regulatory policy. These regulations serve to enhance the quality of our environment in order to promote the public health and welfare and the productive capacity of our Nation's population.

The Health Effects Research Laboratory, Research Triangle Park, conducts a coordinated environmental health research program in toxicology, epidemiology, and clinical studies using human volunteer subjects. These studies address problems in air pollution, non-ionizing radiation, environmental carcinogenesis and the toxicology of pesticides as well as other chemical pollutants. The Laboratory develops and revises air quality criteria documents on pollutants for which national ambient air quality standards exist or are proposed, provides the data for registration of new pesticides or proposed suspension of those already in use, conducts research on hazardous and toxic materials, and is preparing the health basis for non-ionizing radiation standards. Direct support to the regulatory function of the Agency is provided in the form of expert testimony and preparation of affidavits as well as expert advice to the Administrator to assure the adequacy of health care and surveillance of persons having suffered imminent and substantial endangerment of their health.

This report documents one aspect of an International effort, supported by EPA, to provide a comprehensive environmental monitoring program to assess the relative risk of environmental hazard to the health and well-being of our population and to aid in the improvement of our environmental quality. This program, the National Environmental Specimen Bank, will serve as an environmental warning system by providing real time chemical analysis of collected specimens. In addition, this system would permit the use of tomorrow's more sensitive and more specific methods of chemical analysis on stored samples. The advantages of such a program will permit us to assess the effectiveness of our present environmental control techniques by monitoring pollutant trends, as well as establishing environmental baseline levels of new pollutants or pollutants of current concern not previously investigated.

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Director,
Health Effects Research Laboratory

ABSTRACT

The U.S. Environmental Protection Agency (EPA) has been concerned about the potential dangers to human health and the environment from the ever increasing influx of new man-made substances into our ecosystem. Since 1974, the EPA has been actively engaged in studying the feasibility of establishing a program, The National Environmental Specimen Bank System (NESBS), that would provide a formalized, systematic approach to assess the environmental impact of these substances at a national, as well as international level. The NESBS would provide real time monitoring, assessing the adequacy of present pollutant control techniques, as well as providing samples for retrospective analyses.

With the realization that the NESBS is a viable concept, both from the standpoint of need and by the availability of present technology, it must be decided if such a system is in fact, feasible to establish and maintain under actual operating conditions. It is proposed, therefore, that a five-year pilot bank program be initiated. During this time, a limited number of samples should be collected, analyzed, and stored in a central facility. The pilot bank program should focus on validating credible collection, storage, and analytical data.

The functioning NESBS should provide future generations with an important resource for evaluating their current environmental status.

This report was submitted in fulfillment of NSF Grant ENV74-19000 A01 by the U.S. Environmental Protection Agency under the partial sponsorship of the National Science Foundation, the National Bureau of Standards and the U.S. Environmental Protection Agency. This report covers the period June, 1974 through May, 1977.

CONTENTS

FOREWORD..... iii

ABSTRACT..... iv

FIGURES

1. NESB PILOT BANK..... 19
2. PILOT BANK SAMPLES..... 21

I. CONCEPTS..... 1

II. HISTORY..... 3

III. ACCOMPLISHMENTS..... 17

IV. INTERNATIONAL PROGRAMS..... 23

V. CONCLUSIONS AND RECOMMENDATIONS..... 25

BIBLIOGRAPHY..... 26

I. CONCEPTS

Chemicals are an important part of our daily lives. Like many things, however, chemicals have both good and bad effects. Thus, while some chemicals in trace amounts are essential to human life, others can be deadly. For example, scientists discovered that asbestos and vinyl chloride, two chemicals commonly used to make a variety of consumer goods, caused cancer in workers some 20 to 30 years after they were exposed to the substances. And recently, consumers learned that chlorine, which is routinely added to drinking water in many municipalities to kill disease-causing bacteria, apparently reacts with chemical pollutants in the water to form barely detectable, but potentially dangerous, amounts of carcinogenic agents.

These examples are only two of the discoveries made possible in part because scientists have developed more sensitive, accurate ways of detecting and measuring trace chemicals present in very low concentrations in food, tissues, water and air. Now people are beginning to wonder which of the allegedly harmless chemicals in our present day environment might prove to be health hazards.

Finding an answer to this question is the major reason that the Environmental Protection Agency (EPA), the National Bureau of Standards (NBS) and the National Science Foundation (NSF) are studying the feasibility of establishing a National Environmental Specimen Bank System (NESBS). The NESBS would provide a formalized, systematic approach to assess the environmental impact of these substances at a national as well as an international level.

The concepts of the NESBS, real time monitoring and retrospective analytical capabilities, are derived from its dual function. First,

representative portions of samples included in the bank would be analyzed at the time of introduction to provide real time monitoring and evaluation of pollutant trends. Elevation of these trends would serve as early warning sentinels so that proper control measures could be taken to halt rising human body burdens before irreversible damage could occur.

Second, a specimen bank would enable measurement scientists to use tomorrow's more sensitive and specific methods of chemical analysis on today's samples. The improved measurement methodology would enable health scientists to determine accurate levels for substances that would be either undetectable or poorly analyzed by today's less sensitive methodology. The existence of a specimen bank would provide the opportunity to determine what the body burden of newly recognized toxic substances was in the past and to determine if their levels had changed with time.

It is anticipated that this formalized, systematic approach, defining our current environmental hazards, will replace the present system of randomized studies (often without proper validation) used by many State and Federal regulatory agencies as well as other interested parties in proposing environmental quality standards and limits for control technology. If these types of monitoring programs are to continue, as they must to protect our environment as well as the health of our population, then it is necessary to establish and define the basic scientific information required to sustain such a specimen banking system. The NESBS, when operational, will provide future generations with an important resource for evaluating their current environmental influences.

II. HISTORY

The storage of tissue for analytical measurements is a natural outgrowth of an environmental monitoring system. The need for such a monitoring system was realized in the late 1960's by the National Air Pollution Control Administration, one of the predecessors to the U.S. Environmental Protection Agency, with the initiation of human population studies.

The objectives of these studies, (1) to evaluate existing environmental standards, (2) to quantitate pollutant burdens in exposed populations and, (3) to quantitate health benefits of pollutant control, were addressed by coupling sensitive health indicators to comprehensive environmental monitoring. These studies were conducted in communities representing a pollutant exposure gradient, thus allowing replicated dose response studies over time.

Environmental monitoring was divided into two separate aspects, exposure monitoring and tissue pollutant burden monitoring. Exposure monitoring consisted of ambient air monitoring, whereas pollutant burdens, the levels of environmental residues greater than that required of optimal growth and development, were measured in selected tissues. Exposure monitoring was then correlated with health indicators and covariates to assess the health impact of the various classes of air pollutants.

From the very onset of the human pollutant burden studies, short-term tissue banking became an integral part of this program. A tissue or groups of tissues were collected to test a specific hypothesis. These tissues were stored until they could be analyzed, and were then discarded. As the pollutant burden program expanded, the need for a fully developed tissue banking system became more apparent.

This banking system was envisioned as having a dual function. First, to provide real time monitoring and evaluation of pollutant trends. Second, a specimen bank would enable measurement scientists to use tomorrow's more sensitive and specific methods of chemical analysis on today's samples.

In EPA's continuing effort to establish a National Environmental Specimen Bank, a two day working session was held in February 1973 at EPA's National Environmental Research Center, Research Triangle Park, North Carolina to discuss and propose plans for the establishment of a National Environmental Specimen Bank System.

The broad objectives of this working session were:

1. Establish current trends in human pollutant burdens (short-term banking).

2. Create a specimen bank that would provide retrospective analytical capability (long-term banking).

One major recommendation from the working session was that a sample banking system should be established at the national level that would cross all agency lines and provide human tissues representative of that period in time from which the sample was taken. The proper storage of these tissues would permit retrospective analysis using improved methodologies that were likely to be available.

In 1972, the National Academy of Sciences/National Research Council (NAS/NRC) addressed tissue banking when they stressed the lack of coordination in the numerous programs by components of Federal and State governments, private industry and academic institutions to collect, store and analyze specimens of environmental interest.

In an effort to upgrade the availability and long-term protection of environmental samples and to make the information gathered with each

collection readily available, the Subcommittee on the Geochemical Environment in Relation to Health and Disease (GERHD) of the National Committee for Geochemistry, National Academy of Sciences/National Research Council at their Asilomar Workshop in California (1972) recommended that a group of specialists be convened to study this problem at its Capon Springs Workshop in May 1973.

The concepts from the EPA Specimen Bank Conference were reinforced by the Capon Springs Workshop (May 6-12, 1973). The workshop recognized the need for a NESBS to ensure the continuing availability of a comprehensive collection of scientifically selected environmental specimens and information.

The GERHD proposal envisioned the NESBS as a central coordinating institution, relying on specimens collected from a combination of presently existing single-purpose collections and materials banked under its own collection program. A strict quality control methods standardization program would ensure that items needed for future environmental studies are acquired, validated and properly preserved.

The NESBS could be the mechanism used to continually monitor the environment and assess the effectiveness of control practices. To accomplish this task, the GERHD Workshop set forth the following objectives:

1. Establish mandatory criteria for the sampling, storage, and measurement of the various types of specimens that are to be accepted into the System.
2. Provide historical specimens for: (a) the measurement of contaminants not previously investigated, (b) re-evaluation as analytical methods are improved, and (c) measurements of trends.

3. Make samples available for use in measuring rates of changes of persistent environmental substances (both natural and man-made), through a program of systematic sampling and careful storage of specimens for retrospective examination.
4. Establish a centralized data and information storage and retrieval system appropriate to the scientific community, and to other interested users.
5. Provide samples that can be used in assessing the long-term environmental effects of new industries and technologies, or of other activities.
6. Provide information useful for the assessment of current environmental policies, and for the establishment of revised environmental policies.
7. Establish a framework for national coordination of current and future specimen banks and collection activities to minimize duplication of efforts.
8. Foster cooperation and establish working arrangements for the international exchange of information and specimens.

The GERHD subcommittee concluded that the U.S. Government should establish, on a permanent basis, a National Environmental Specimen Banking System. Initial coordinating and funding of the multi agency system should be considered by the National Science Foundation. The Environmental Protection Agency should be considered as the most logical organization to establish the system.

Four tasks were proposed to begin development of the NESBS.

Task I. Conduct an inventory and assessment of the value of existing specimen collections as potential candidates for participation in the NESBS.

Task II. Establish a steering committee composed of representatives from a variety of concerned groups that are providing funds, participating in specimen collection, and operating monitoring programs. This committee would be responsible for:

1. Developing the organizational and managerial structure of the NESBS.
2. Identifying the types of specimens and information to be stored in the Banking System.
3. Developing interim protocols for sampling, sample handling, and storage of specimens to be included in the bank.
4. A plan for a data handling, storage, and retrieval system.

Task III. Identify research needs as determined during the implementation of the NESBS. Areas already identified are:

1. Sampling strategies
2. Sample processing procedures
3. Measurement strategy

Task IV. Conduct meetings at national and international level, of user and research groups, to exchange current information that would be relevant to the NESBS.

During this time, the rapid growth of EPA's human pollutant burden program dictated the need for a sophisticated system of standardized protocols for sample collection, preparation, storage and analysis.

In December, 1973, this need was addressed by the EPA and the NSF in a meeting to formulate plans for the development of a National Environmental Specimen Bank. At this meeting, a four point proposal was generated, with joint funding being provided by NSF, EPA and NBS.

The four point proposal contained the following elements:

1. Survey of Existing Specimen Collections
2. Evaluation of Specimen Collection Survey
3. Research protocol development
4. Planning document for the organization and management of the NESBS

1. Specimen Collection Survey

The initial phase of the specimen bank program, the specimen collection survey, was designed to provide a broad data base on the various aspects of specimen banking. This data base would subsequently be utilized in developing guidelines for the NESBS. Oak Ridge National Laboratory, working through an interagency agreement with EPA, has conducted a national survey of existing specimen collections in an attempt to identify those places in the Continental United States that are currently, or have been storing material collected in either research or monitoring activities. The survey objectives were to identify, (1) where collections were located, (2) who maintained the collections, (3) what the collections consisted of, (4) what analysis had been performed on the material in the collections, (5) how the sample collections had been preserved and stored, and (6) the accessibility of the stored materials and associated data to both research and regulatory personnel. The survey was designed to include collections in the following areas: geological, atmospheric, human tissues, plant and animal tissues and water samples. The survey began in May, 1974 and was completed in August 1975. Of the 4506 letters of survey intent that were

mailed, 649 positive responses were compiled into the data base (Van Hook and Huber, 1976).

2. Specimen Collection Evaluation

NBS has critically evaluated the results of the survey as to their utility and applicability to the NESBS. Few of the survey respondents answered the questions in sufficient detail to give a definite answer, but most of the collections could be of use for taxonomical purposes.

In developing guidelines for the evaluation of this survey, a large portion of the recent literature concerning sampling and storage of environmental specimens has been examined. In addition, the advice and opinions of workers in various aspects of the field has been obtained.

It became readily apparent from the conflicting data in the literature, that additional research must be conducted in the areas of sample handling and preparation. Gross contamination of the samples, from the time of the sample collection stage, through the analysis stage, appears to be a major problem (Becker and Maienthal, 1977) and (Maienthal and Becker, 1976).

3. Protocol Development

For a system such as the NESBS to be of any value, the credibility of the methodology protocols must be above reproach. EPA realized this condition at the conception of the NESBS plan, and it has been working with the National Bureau of Standards in the development of state-of-the-art methodology for sampling, sample handling, analysis and long-term storage.

It is anticipated that this formalized, systematic approach will be invaluable to EPA in defining our current environmental hazards, and in addition, the methodology protocols would be readily available to other interested user groups.

Since January 1975, the Analytical Chemistry Division of the National Bureau of Standards has conducted a continuing research program to improve methodologies for the collection, storage, and analysis of NESBS samples.

The program currently underway is pursuing an active research program to improve methodologies for sampling, sample handling, and storage of biological and environmental samples for analytical purposes, as well as evaluating and improving analytical techniques to be used for the analysis of the trace constituents of interest. These portions of the NBS research program are currently directed primarily towards trace elements, but future research will be directed toward other substances of interest, such as trace organic species.

A major portion of the current NBS research program has been the experimental evaluation of contamination and losses of the trace constituents of interest during sampling, sample handling, and long-term storage. One of the initial projects in this program was the evaluation of twelve polymeric materials for their trace element content, and for the possibility of removing these trace elements when contacted by liquid samples. This study was made using three complimentary trace analytical techniques, neutron activation analysis, atomic absorption, and spark source mass spectrometry. The utilization of a multidisciplinary analytical approach gave an almost complete coverage of trace elements of interest.

The results of this study indicated that many materials were grossly contaminated by trace elements from plasticizers, formulators, and other process materials. However, conventional polyethylene and Teflon were found to be reasonably clean and it was generally found that less than ten percent of the bulk trace element content could be leached out, even

with conditions as severe as a 2-hour hot leach with 6N acid.

A second, and equally important part of the current research program has been a study and evaluation of long-term storage techniques which would be adequate for tissue and other biologically active samples. The effects of microbiological action on trace constituent concentrations and distributions are well documented. However, the mechanism for complete long-term elimination of that micro-biological activity is not well documented. Freezing has long been applied as a technique for analytical storage, however no study has yet been performed to document the reliability of this method of storage for more than a short period of time.

More recent studies into lyophilization have demonstrated minimal losses and/or contamination of trace elements during the sample processing. The NBS has now documented the viability of the freeze-drying technique to stabilize trace element composition. Standard Reference Material Bovine Liver (SRM1577) has been shown to be unchanged for more than five years. The bulk meterial for this SRM was freeze-dried, ground, blended, and bottled. This material was analyzed and certified for trace element composition in 1972. To the present time, no documented evidence of trace element loss or alteration has occured.

Finally, the technique of low temperature ashing (LTA) has been evaluated for long-term storage and found to have many advantages. A recent study at NBS investigated the loss of trace elements during plasma ashing using both radioactive tracers, and activation analysis of samples before and after ashing. The results obtained indicate that over thirty (30) trace elements are retained quantitatively during LTA. Five elements, mercury,

osmium, and the halogens (chlorine, bromine, iodine), are not quantitatively retained. It was also determined from the above studies that contamination of the sample was not a measurable problem during ashing. An added advantage to the LTA technique is that resultant samples are easily composited and homogenized.

The latter portion of the current research program has been to evaluate the effectiveness, and improve where necessary, the major analytical techniques for environmental samples. The elements specified to be of primary interest were mercury, lead, arsenic, selenium, nickel, vanadium, copper, manganese, beryllium, chromium, platinum, and palladium.

4. Planning Document for the Organization and Management of the NESBS

The formulation of a plan for the development and operation of the bank will require a series of interrelated tasks. Some tasks have been considered in detail, while others are still in the planning stage. The actual completion of the NESBS planning document will have to await the outcome of the Five Year Pilot Bank Program. The various tasks that will be considered in preparing the planning document will include:

a. Review of the Problem:

An identification and description of the issues which create the need for an NESBS. The kinds of environmental insults and dangers which could be better managed and the kinds of analyses required to assess the magnitude and trends of such dangers will be described. In addition, the contribution that such a bank could make to better environmental management, will be estimated. The result of this task will be a statement of need, including the types of information that would be generated, their various applications as well as a thoroughly documented rationale for the bank.

b. Development of Specific Bank Objectives:

Based on the rationale and need, a set of specific objectives will be developed to identify just what functions the NESBS will be expected to perform and how it will meet the needs specified in Task a.

c. Identify and Specify Sample Type:

The types of specimens that will be collected as well as the areas of collection and trophic levels to be sampled will be based upon existing and anticipated future needs and objectives as stated in Task b. Specifications of the kinds of demographic and technological data which must accompany the samples will be developed.

d. Evaluate and Formulate Methods of Analysis:

Analytical procedures applicable to the NESBS will be evaluated. Preferred methodology will be specified along with the amount and condition of sample required to perform such an analysis.

e. Analysis of Specimen Collection, Preparation and Storage Requirements:

Based upon the kinds and amounts of specimens and the required storage condition of samples (so as to maintain their usefulness) the procedures available for collection, preparation and storage will be analyzed and the preferred methods and procedures will be identified. In addition, the total amounts of specimens to be stored will be estimated.

e. Analysis of Users:

An identification, analysis and evaluation of potential users will be undertaken to provide a set of user specifications as an input to

the design of the system and the establishment of operating procedures. Additionally, a set of guidelines will be established to govern who can use the bank and what may be taken from it.

g. Design, Physical Make-up and Location of the NESBS:

Tasks b through e will provide the basic information upon which to establish the functional specifications of the system and will allow for the development of a system design.

The physical make-up will depend substantially upon the numbers and volumes of specimens, the methods of storage, the analytical instrumentation and laboratory requirements, and the numbers and kinds of people who will be provided access to the system.

The location will depend substantially upon the location of the users, the location of the sample sites, and to an as yet undetermined degree, upon what now exists which may become a part of the system.

h. Design of a Data Storage and Retrieval System:

The utility of the NESBS will be expressed by the collection, maintenance, processing, and dissemination of data. This data system, whether an existing off-the-shelf system, or a new set of system specifications will be based upon user requirements and specimen sample requirements. These requirements will be translated into more meaningful parameters for the design of the data storage and retrieval system. These considerations will include: data volume and compression for storage, frequency of user access to data, updating amending data, data format, data

processing, and data traceability. The NESBS requirements may dictate a mix of data storage media and associated access systems to be most cost-effective. This mix could consist of:

1. Photographic storage media (microfilm and microfiche)
2. Hard copy volume
3. Digital storage media with interactive and non-interactive modes

i. Develop a Plan for Management and Operation of the Bank:

The management and operation plan for the NESBS will consider the following: the maintenance requirements of the physical building(s) housing the bank, the storage facility and the data storage and retrieval system; the procedural requirements for the use of the bank, insuring the economic utilization by the users; outline of NESBS support requirements; formulation of a management plan acknowledging the EPA as the lead agency with unambiguous authority for insuring that the NESBS meets its objectives by satisfying the user's needs, and recognition of the need to update the specimen and data base.

j. Budget Plan:

The budget plan will take into consideration the one-time set up costs at the inception of the NESBS and then identify all of the cost elements and their contribution to the total maintenance costs.

At the present time, NBS is developing state-of-the-art methodology for sample collection, preparation, storage and analysis, thus satisfying the requirements of tasks d and e. In addition, NBS and EPA have prepared documentation addressing Tasks a,b,c, and f. Tasks a,b,c and f are regarded

as the statement of need, or feasibility study (Rook and Goldstein, 1977). The successful completion and acceptance of these tasks would warrant the completion of tasks g through j.

The tasks required to develop the NESBS have been designed to give the maximum amount of information in a step-wise fashion while remaining cost effective. Each series of tasks terminates at a GO-NO GO stage, with the exception of the methodology tasks. As a result of the urgent need for methodology protocols and the extended time required for the decision to develop the NESBS, the methodology protocols will continue until the final GO-NO GO stage. It is my opinion that regardless of the outcome of the NESBS, the methodology protocol development would provide the scientific community with state-of-the-art standardized protocols for sample collection, preparation, storage and analysis for a diversity of elements and chemicals in a variety of ecologically important materials. The cost benefit of this alone is uncalculable.

The initial survey and evaluation task which provided us with the present status on specimen collections and sampling, storage and analysis techniques cost approximately $100,000.00. Protocol development for sampling, specimen preparation, storage and analysis is currently costing about $200,000.00 per year. The preparation of the NESBS need statement cost about $50,000.00.

It is estimated that the remaining tasks g through j may cost about $300,000.00 to $400,000.00. These tasks would provide detailed descriptions for the physical design of a banking system, a data storage and retrieval system, operation and management plan and an operation budget.

III. ACCOMPLISHMENTS

On 19 and 20 August, 1976, the NBS and U.S.EPA co-sponsored a workshop to review technical developments and to make recommendations on the implementation of the NESBS. The Workshop consisted of a review session where past specimen banking considerations were discussed; a technical session where recent analytical research relevant to sample banking was discussed; and a planning session where planning and design of a prototype banking system was outlined.

On review of the issues that created the need for the NESBS, there was unanimous agreement that not only was the concept of sample banking still of vital importance to the assessment of low-level environmental contaminiation but that many of the original issues which mandated the implementation of the NESB were heightened due to recent environmental pollutant episodes. The kepone episode in the James River and the Chesapeake Bay was pointed to as a prime example were existing specimans of documented validity would have been extremely useful to assess the change in the environment of that pollutant. There were not and are not samples of aquatic life or shell fish available from the Chesapeake Bay or James River which can be used for determination of Kepone levels before the start-up of the Kepone production in that area. Limited samples were available from the Virginia Institute of Marine Sciences dating back 3-4 years. These samples have proven invaluable in establishing the extent to which Kepone has affected the marine life. Had earlier samples been available from a banking system, a far better assessment of Kepone baseline levels prior to the dumping episodes would have been available

to environmental officials. With the large increase of man-made chemicals now being put into our environment, it is evident that issues such as the Kepone insult in Virginia are surely to be on the increase rather than to remain as an isolated situation.

The single most important point to come from the Workshop was that the NESBS can serve many important functions, not just that of long-term retrospective analysis. The results of sample banking would surely impact on monitoring and health effects research of the EPA, and would be of great assistance to ongoing programs within the Department of Agriculture, Food and Drug Administration, and other agencies.

A set of specific objectives for the sample bank were identified. (Figure 1) Those objectives are summarized as follows:

1. The collection, preservation, and storage of selected environmental samples using methodologies that had been documented to minimize or eliminate alteration of trace constituents.
2. The real-time analysis of selected trace constituents using methods of documented validity to obtain monitoring trend data.
3. Research in analytical methodology utilizing both the accumulated long-term data base and samples that have been stored in the NESBS. This research will lead to a self-improving set of monitoring data.
4. The periodic review of the operation of the banking system relative to its valid input of samples and output of analytical data.

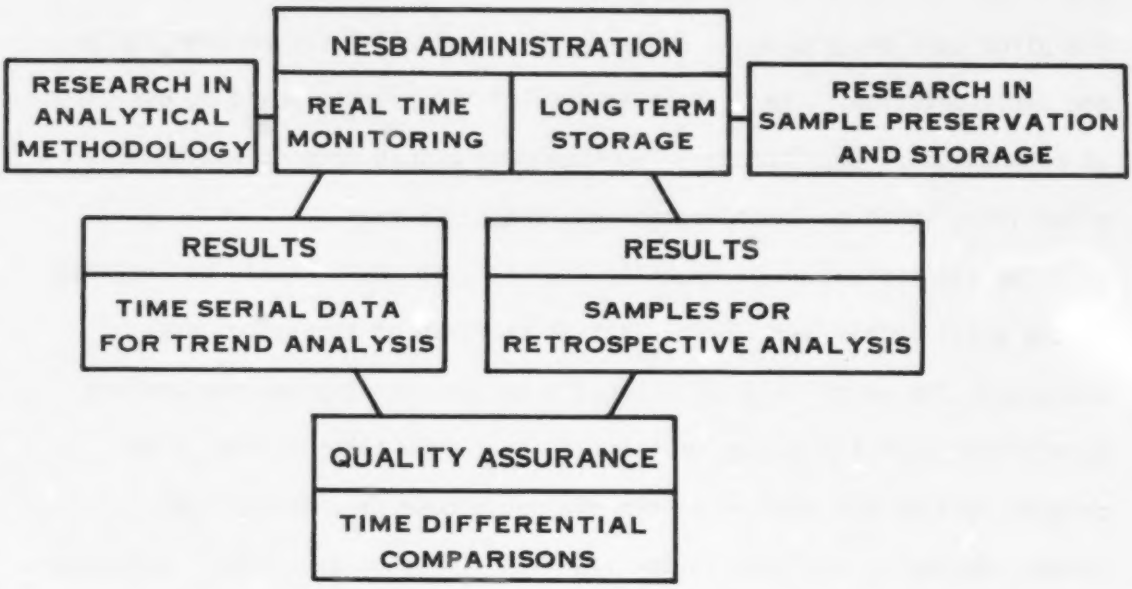

Figure 1. NESB PILOT BANK

The conclusions expressed by the Workshop participants was that a formalized, systematic approach is needed to assess the environmental impact of the ever increasing influx of man-made substances into our ecosystem. The technology to initiate this type of program is presently available and should be formulated into a pilot bank program. This program would utilize and integrate our newly developed techniques with those currently used. The pilot bank program would serve as the "test site" for program design and implementation. The various aspects of the program would be evaluated at each stage of development. The knowledge gained from operating this pilot study would be incorporated into the NESBS plan.

The identification of specific sample types which should be included in the pilot sample bank during initial start-up of the system was discussed. The major focus of attention was on the absolute requirement to minimize both the number of samples and sample types in the pilot program so that the banking system did not become overwhelmed with either samples or analyses during its first years of operation. Unreasonably large numbers of avoidable errors would destroy its credibility before it was even in full operation.

Thus, all participants recommended the inclusion of a modest sample set per year for the first five years of operation with the focus on validating credible storage and analytical results.

A reasonable figure of approximately two thousand samples a year, split into four matrix types, was recommended (Figure 2). Also, it was

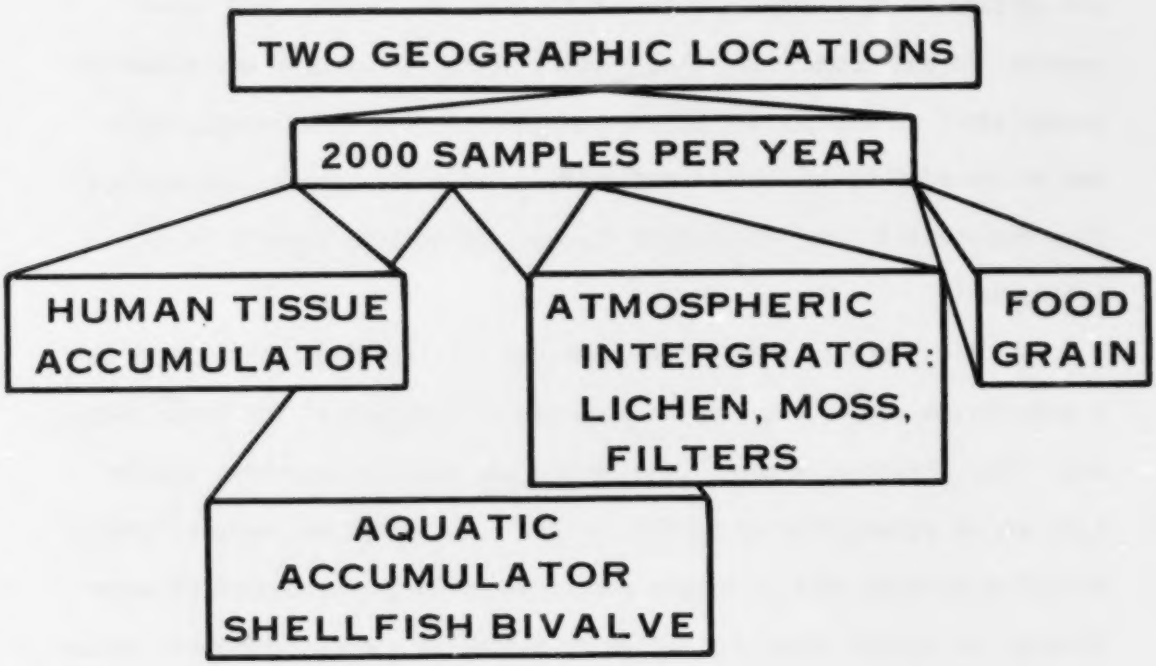

Figure 2. PILOT BANK SAMPLES

recommended that the samples be obtained from no more than two different locations in the beginning phases, to minimize problems with logistics, sample collection, and transport.

Nine different sample types representing all major phases of environmental samples were considered for inclusion in the bank. These included air particulates, sediment, water, botanical, biological, and human samples. It was recommended that samples which represented environmental accumulators or integrators be emphasized as initial candidates, both due to the ease of analytical manipulation of those samples and because they represented time integrators of major pollutants present in our environment.

The first sample that was recommended for inclusion unanimously was a soft tissue sample that had an accumulator function in the human body, most likely liver or kidney. The second and equally important sample type was an accumulator of aquatic origin. Agreement was reached that a shellfish bivalve such as oyster which passes large quantities of water through its system every day and which tended to mirror increased concentrations of many toxic pollutants was a good choice. The third sample type was a food material representing a major input into the human diet. Consensus was unanimous that a food grain or composite of grains was the best choice. The fourth sample type was a collector of atmospheric or airborne pollutant materials. It was recommended that material such a lichen or moss was a good indicator of long-term trends in atmospheric pollutants and should be included in the initial bank. These four sample types were chosen for their diversity and their utility to environmental

monitoring programs. However, a second and even more important consideration was that there is now enough scientific evidence to be reasonably assured that the storage and analysis of the trace element components in these materials could now be carried out with integrity (Rook and Goldstein, 1977).

One of the last items for consideration at the Workshop was the evaluation and formulation of viable analytical methods for the real-time and retrospective analysis of samples from the NESBS system. Part of the NBS research effort has been to publish a compilation of analytical methods currently being used for SRM certification analysis. These methods will be available in the near future.

The concept of specimen banking to assess the environment was reinforced at an International Workshop "The Use of Biological Specimens for the Assessment of Human Exposure to Environmental Pollutants" held in Kirchburg, Luxembourg, 18-22 April, 1977 (Goldstein, 1977).

The conclusions and recommendations from this Workshop stated that where the scientific expertise is already available, that biological monitoring should be instituted to provide direct evidence of human exposure to chemicals in the environment. In addition, research should be instituted in those areas where the scientific expertise is lacking or insufficient.

IV. INTERNATIONAL PROGRAMS

The problems of environmental pollution are worldwide in scope and transgress all national and political boundaries. Finding answers to problems of environmental concern in areas of pollutant identification, sources, effects, control, etc. are the concerns of many nations.

Since 1975, the United States Environmental Protection Agency and the Environmental Agencies of the Federal Republic of Germany (FRG) have been pursuing collaborative research in areas of the tissue bank program as part of a bilateral agreement on the environment. This cooperative program allows for the input of expertise from the two countries, thus reducing research time and cost. During this time period, the U.S. effort has focused on research areas related to trace elements, whereas, the FRG has concentrated their efforts in the area pertaining to organic substances.

Meetings are held on a yearly basis to discuss and exchange research findings.

V. CONCLUSIONS AND RECOMMENDATIONS

1. The National Academy of Sciences/National Research Council stressed the lack of coordination in the numerous programs by components of Federal and State government, private industry and academic institutions to collect, store and analyze specimens of environmental interest.
2. A formalized, systematic approach, defining our current environmental hazards, must replace the present system of randomized studies (often without proper validation) so as to protect our environment as well as the health of our population.
3. It is necessary to establish and define the basic scientific information required to sustain a specimen banking system.
4. The conclusions and recommendations of two workshops (NBS/EPA - Aug. 1976 and WHO/CEC/EPA - Apr. 1977) proposed that where the scientific expertise is already available, that biological monitoring should be instituted to provide direct evidence of human exposure to chemicals in the environment.

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